DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

cc: HFI-35/FOI Staff
DWA

September 5, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 58

Vickie Rengstorff
Acting President
Vision Pharmaceuticals, Inc.
1005 Glenangus Drive
Bel Aire, Maryland 21015

Dear Mrs. Rengstorff:

During an inspection of your manufacturing facility located in Mitchell, SD, conducted on July 28-30, 1997, and August 5-7, 1997, our investigators documented deviations from the Current Good Manufacturing Practice Regulations (GMPs) noted in Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211) in conjunction with the manufacture of the sterile eye lubricant VIVA-DROPS. These GMP deviations cause your drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Prior to concluding the investigation, a 17-item list of objectionable conditions (FDA-483) was presented to and discussed with Ms. Kathleen Baade, Laboratory Director, and Ms. Mary Tiede, Assistant Laboratory Director. These violations include:

1. Poor employee practices in sterile fill operations.

2. Failure to adequately validate the manufacturing process for your product.

3. Failure to provide appropriate laboratory testing to determine conformance to sterility requirements.

4. Failure to provide documentation to assure proper performance of filling equipment.

5. Stability testing was not performed at the required intervals for your active ingredient.

6. Expiration dates of product improperly assigned.

7. Failure to provide an adequate written program for stability testing.

Please refer to the August 7, 1997, FDA-483 for a more complete listing of the drug GMP violations noted during this investigation. The above identified violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure your operations are in compliance with local and federal regulations.

Until these violations are corrected, FDA will recommend against the award of contracts to other Federal agencies or the approval of pending Premarket or New Drug Applications.

We have received your response, dated August 25, 1997, to the FDA-483 Inspectional Observations. The corrections you outlined in your response appear to be satisfactory. We expect all corrections will be completed no later than December 1, 1997. Please respond within 15 working days of receipt of this letter, confirming that your responses to the items cited on the FDA-483 are accurate and the schedule for completion of the corrections has not changed. If corrective action cannot be completed by December 1, 1997, please state the reason for the delay and the time within the corrections will be completed.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and injunction.

Any questions regarding this matter should be directed to Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead. Ms. Hoffman may be reached at (612) 334-4100 ext. 159.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl

xc: Kathleen M. Baade
Laboratory Director
Vision Pharmaceuticals
1022 North Main Street
Mitchell, SD 57301